24. (New) A method according to claim 2 wherein at least a portion of the surface of said particles is coated with a surfactant coating that increases the binding efficiency of said particles with fibrin.

25. (New) A detectable reagent of claim 11 wherein at least a portion of the surface of said particles is coated with a surfactant coating that increases the binding efficiency of said particles with fibrin.

REMARKS

Claims 1, 2, 11 and 20 have been amended to more particularly point out and distinctly claim the present invention. Specifically, Applicants request addition of the step "binding at least a portion of said particles to at least a portion of said fibrin" to the methods set forth in claims 1 and 2. Similarly, Applicants request addition of the step of "binding at least a portion of said particles to said fibrin site" to the method claimed in claim 20. Support for these amendments is found in the as-filed Specification on page 2, line 20, and in Examples 1, 4, 6 and 7. In addition, Applicants request addition of the functional limitation of "at least a portion of said particles selectively bind to fibrin with a binding efficiency greater than the binding efficiency of said particles with other blood plasma proteins" to the detectable reagent of claim 11. Support for this amendment is found in the as-filed Specification on page 10, line 10, and in Examples 4 and 5. New claims 23-25 are drawn to embodiments of the present invention wherein there is a surfactant coating that increases the binding efficiency of the reagent particles to fibrin. Support for new claims 23-25 is found in the as-filed Specification on page 6, line 29, to page 7, line 2, and in Example 16. None of the amendments made herein constitutes the addition of new matter.

Election/Restriction

The Office Action identifies Groups I and II as related as product and process of use and cited MPEP section 860.05(h) which states:

"A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product, or (B) the product as claimed can be used in a materially different process."

Specifically, the Examiner alleged that [i]n the instant case the reagent can be used in a materially different process other than the detection of fibrin" and, therefore, concluded that 'restriction for examination purposes . . . is proper." While applicants agree that claims 11-19 may be defined as a product comprising a detectable marker encased in a plurality of layers of carbon and that claims 1-10 and 20-25 may be defined as a process of using that product, the Examiner's reliance on MPEP section 860.05(h) appears to be misguided. The present application was filed under 35 U.S.C. 371. As noted by MPEP §1893.03(d), "unity of invention (**not restriction**) practice is applicable in . . . national stage (filed under 35. U.S.C. 371 APPLICATIONS." Accordingly, restriction practice as prescribed MPEP §860.05(h) is not properly application to a determination of unity of invention. Therefore, the restriction requirement is improper and its withdrawal respectfully requested.

The Office Action also alleges that "[t]he inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because . . . they lack the same or corresponding special technical features. " Specifically, the Examiner concluded that there is not unity of invention because "the reagent can be used in a materially different process other than the detection of fibrin.

MPEP section 1893(d) governs unity of invention practice for national stage applications filed under 35 U.S.C. 371 and provides:

"[w]hen making a lack of unity of invention requirement, the examiner **must** (1) list the different groups of claims and (2) explain why each group lacks unity with each other group . . . specifically describing the unique special technical feature in each group."

Although the Examiner asserts that Groups I and II lack unity with each other, the requisite description of the unique technical features in each group is not present. Accordingly, the finding of a lack of unity of invention is improper, and withdrawal is respectfully requested.

The processes and detectable reagents set forth in the amended claims, however, do possess the requisite technical feature in common which provides unity of invention. Section 1.475 of 37 C.F.R. sets forth the appropriate standard for evaluating unity of invention and provides:

> "the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features."

Amended claims 11-19 relate to detectable reagent particles that **selectively** bind to fibrin and amended claims 1-10 and 22-25 relate to methods of detecting fibrin by **selectively** binding the aforementioned detectable reagent particles thereto. Accordingly, it is the selective binding ability of the claimed particles that defines their critical functional properties and that enables their use for selective detection of fibrin in sources such as blood or plasma which contain a large number of potentially interfering proteins. The amendments requested above clarify this functional limitation in both processes and reagent claims. Accordingly, the selective binding of the reagent particles to fibrin is the technical feature common to both reagent and process claims, and this common technical feature mandates a finding of unity of invention.

Further, the selective reactivity of the claimed reagent particles makes them "specifically designed" for carrying out the methods of the amended claims. MPEP section 1893.03(d) expressly recognizes unity of invention of means "specifically designed" for carrying out a claimed process. In addition, this section explicitly directs that such specifically designed means "does not imply that the . . . means could not be used for carrying out another process, nor does it imply that the process could not be carried out using an alternative . . . means." Accordingly, the

alleged existence of "materially different process[es]" using the claimed reagent particles does not itself create an inference of an absence of unity of invention for claims 1-25.

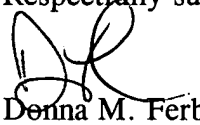
In view of the foregoing, it is submitted that the lack of unity of invention is improper. Accordingly, reconsideration and withdrawal of the lack of unity of invention is respectfully requested.

Conclusion

Based on the foregoing, this case is considered to be in condition for allowance and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

Respectfully submitted,



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Attorney docket No.5-00
bmk: November 21, 2001

Marked up version of amended claims in attached Amendment.

Docket No.: 5-00
USSN 09/463,082

1. (Once amended) A method for the in vivo detection of fibrin in a patient, said method comprising the steps of:

administering to said patient an effective amount of a detectable reagent comprising a plurality of discrete particles dispersed in a pharmaceutically of veterinarily acceptable carrier, diluent, excipient, [and/or] adjuvant or any combination thereof, wherein at least some of [each of] said particles comprise [comprising] a detectable marker encased in a plurality of layers of carbon and are capable [being capable] of binding to fibrin; [and]

binding at least a portion of said particles to at least a portion of said fibrin; and

detecting the presence of said detectable marker in said patient.

2. (Once amended) A method for the detection of fibrin in a source, said method comprising the steps of:

supplying to said source a detectable reagent comprising a plurality of discrete particles dispersed in a carrier, diluent, excipient, [and/or] adjuvant or any combination thereof, wherein at least some of [each of] said particles comprise [comprising] a detectable marker encased in a plurality of layers of carbon and are capable [being capable] of binding to fibrin; [and]

binding at least a portion of said particles to at least a portion of said fibrin; and

detecting the presence of said detectable marker in said patient.

11. (Once amended) A detectable reagent for use in the in vivo or in vitro detection of fibrin, said detectable reagent comprising a plurality of discrete particles dispersed in a carrier, diluent, excipient, [and/or] adjuvant or any combination thereof, wherein at least some of [each of] said particles comprise [comprising] a detectable marker encased in a plurality of layers of carbon, wherein at least a portion of said particles selectively bind [being capable of binding] to fibrin with a binding efficiency greater than the binding efficiency of said particles with other blood plasma proteins.

20. (Once amended) A method of targeting a drug to a fibrin site in vivo, the method comprising the steps of:

administering to a patient an effective amount of a reagent comprising a plurality of discrete particles dispersed in a veterinarily or pharmaceutically acceptable carrier, diluent, excipient, [and/or] adjuvant or any combination thereof, wherein at least some of [each of] said particles comprise [comprising] a plurality of layers of carbon and are capable [being capable] of binding to fibrin and at least some said particles [having] have coupled thereto a drug to be targeted to the fibrin site; and

binding at least a portion of said particles to said fibrin site.